

**REMARKS**

Claims 11 and 14-25 were pending in the present application. Claims 14-16 and 21-25 have been withdrawn from consideration. Claim 11 has been amended herein, support for which can be found at, for example, page 2, lines 7-20 of the underlying PCT publication. Upon entry of the present amendment, claims 11 and 17-20 will remain pending.

**I. The Claimed Invention Is Not Obvious**

Claims 11 and 17-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Ortlepp et al., Eur. J. Pharmacol., 2002, 436, 145-150 (hereinafter, the “Ortlepp reference”) and Yoneyama et al., Jpn. J. Pharmacol., 2002, 89, 193-196 (hereinafter, the “Yoneyama reference”) in view of STN, RN 133240-46-7, 1991 (hereinafter, the “STN reference”). Applicants traverse the rejection and respectfully request reconsideration because the combination of cited references fails to produce the claimed invention.

The combination of the cited references fails to produce Applicants’ claimed methods, as amended herein. For example, the combination of cited references does not teach or suggest treating a human. Indeed, the Ortlepp reference reports a study comparing the effect of an ACE inhibitor and the effect of an angiotensin II inhibitor on hypertension, cardiac hypertrophy, hyperinsulinemia and atherosclerotic plaque in mice. Thus, the Ortlepp reference is irrelevant for the present invention, which regards humans.

In addition, the combination of the cited references fails to teach or suggest treating a human having a blood pressure over 140/90 mmHg, which is a feature recited in Applicants’ claims. The baseline for the mice in the study disclosed in the Ortlepp reference is about 110/73.

Further, one of the features of the presently claimed methods may be having a body mass index above  $30 \text{ kg/m}^2$ . To calculate body mass index, the weight of the patient, in kilograms, is divided with the length of the patient multiplied by itself, measured in meters. Obviously, body mass index in the WHO definition of the metabolic syndrome, does not apply to mice. Even further, there is no baseline given in the Ortlepp reference for plasma triglycerides, which is recited in the claimed methods. For placebo, it is given at a level lower than the definition of a human diagnosed with metabolic syndrome would have. There is no teaching or

suggestion in the Ortlepp reference of what the threshold would have been, would there have been a definition for metabolic syndrome in mice.

Thus, the Ortlepp reference does not disclose treatment of the metabolic syndrome in a human having the features recited in claim 11. The other cited references fail to cure this deficiency. Provided with these facts, a person skilled in the art would not draw any conclusions as to the usefulness of angiotensin II inhibitors for treating metabolic syndrome. Therefore, the claimed invention is not obvious in view of the combination of cited references. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

**II. Conclusion**

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Office is invited to contact Applicants' undersigned representative at 610.640.7859 if there are any questions regarding Applicants' claimed invention.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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